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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,876	02/11/2004	Ashley Edward Fenwick	P32296D1	3320

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GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939

EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,876	FENWICK ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 6-12 and 15 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5,13,14,16-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 10/030,661.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Claim Objections

1. Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because it depends on itself. See MPEP § 608.01(n). Accordingly, the claim 6 not been further treated on the merits.

2. Claims 7-12 and 15 are objected to under 37 CFR 1.75(c) as being in improper form because they depend on claim 6 which is an improper multiple dependent. See MPEP § 608.01(n). Accordingly, the claims 7-12 and 15 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5, 13, and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. In claim 1, the definition of R^1 recites the phrase, "*as a single substituent, optionally in combination with a further substituent as hereinbefore defined.*" It is

unclear how the substituents in the combination are connected with each other, and how many substituents are in such a combination.

b. Also, in claim 1, the definition of R^9 and R^{10} recites limitations of "*aryl, **e.g.**, phenyl, or aralkyl, **e.g.** benzyl, **for instance** morpholine or piperazine*". The symbol "*e.g.*" and the phrase "*for instance*" render the claim indefinite because it is not clear if the limitation following said phrase is a part of the claim. See M.P.E.P. 2173.05(d).

c. Also, in claim 1, the definition of R^{12} recites the limitation of "*such as CH_2OH from serine*" which renders the claim indefinite because it is not clear if CH_2OH is the only intended side chain, or side chains of other amino acids are intended as well.

d. Claim 5 lacks antecedent basis for reciting "*2-oxo-pyrimid-5-ylmethyl*" which is not recited for R^1 in claim 4 or claim 1. Note, in claim 1, "*oxo*" is not a substituent on R^1.

e. Claim 13 refers to Examples 1-157, which renders it indefinite because it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

f. Claim 16 is a substantial duplicate of claim 1 because it depends on claim 1 for the structure, but also recites the intended use of "*for use in therapy*", which does not have significant patentable weight.

g. Claim 18 defines diseases in term of its mechanism which renders its scope vague and indefinite because such a limitation reads on diseases that have yet to be discovered.

h. Claims 2-5 and 16-20 are (also) rejected as being dependent on claim 1 and carrying over its indefinite limitations.

i. **Use:** Claim 17 provides for the use of a compound of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Use Claim: Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Scope of Enablement:** Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of atherosclerosis, does not reasonably provide enablement for the treatment of a disease state associated with "*activity of the enzyme L_p-PLA_2*". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claim 18 recites a method of treating "*a disease state associated with activity of the enzyme L_p-PLA_2*" which, according to the instant specification, covers the treatment of atherosclerosis, diabetes, hypertension, angina pectoris, after ischaemia and reperfusion, rheumatoid arthritis, stroke, Alzheimer's disease, myocardial infarction,

reperfusion injury, sepsis, acute and chronic inflammation, and schizophrenia. Thus, the claimed method covers the treatment of the heart, joints, pancreas, liver, brain, which is a very broad scope of treatment.

The amount of direction or guidance presented: The enzyme L_p-PLA_2 is an enzyme lipoprotein associated phospholipase A_2. The specification provides only one *in-vitro* biological assay which is not conclusive if the claimed compound could treat any disease. Based on the relationship between lipoprotein and atherosclerosis, the treatment of atherosclerosis can be established. However, for other diseases such as diabetes, Alzheimer's disease, rheumatoid arthritis, sepsis, schizophrenia, etc., there is no evidence if this compound can lower blood sugar, increase motion, improve memory, balance mood, etc. Therefore, the specification fails to provide enablement for the full scope of treatment recited in the instant claim 18.

The state of the prior art: Currently in the practice of medicine, agents that affect LDL (low-density lipid) are not used to treat diabetes because they do not lower blood sugar. Likewise, said agents are not used to treat rheumatoid arthritis, Alzheimer's disease, sepsis, schizophrenia, or any other diseases because there is no relationship between LDL (low-density lipid) and other diseases.

The relative skill of those in the art: Even with the advanced training, the skilled clinician would have to engage in undue experimentation to establish data that would adequately support the use of the claimed compounds in the treatment of diseases other than atherosclerosis. Such a task would require a tremendous amount of effort, time and resources.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting path ways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification only shows evidence that the claimed compounds can inhibit L_p-PLA_2, and therefore, can treat atherosclerosis. However, said evidence does not adequately guide the skilled clinician in the treatment of other diseases that are allegedly related to L_p-PLA_2 such as: diabetes, rheumatoid arthritis, Alzheimer's disease, sepsis, schizophrenia, etc. Thus, with such a limited teaching, the skilled clinician would have to carry out undue experimentation to use the claimed compounds in the methods recited in claim 18.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 14 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14 and 19 of copending

Application No. 10/030,661 (recently allowed). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 14 of the copending application recites one species that is also the last species recited in the instant claim 14. The instant claim 14 differs from claim 14 of the copending application by reciting other species as well. Thus, it would have been within the level of the skilled chemist to select same species recited in claim 14, and use it to treat atherosclerosis as well.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No pending claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tamthom N. Truong
Examiner
Art Unit 1624

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4-29-05

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600